

statement of formula or a reaction or interaction between the pesticide product being repackaged and the residue remaining in the container.

(g) *How must my individual establishments clean a refillable container that has a broken (non-intact) tamper-evident device or one-way valve?* As required in paragraph (f) of this section, a refiller at your establishment must clean each refillable container that has a tamper-evident device or one-way valve that is not intact by conducting the pesticide product's refilling residue removal procedure before repackaging the pesticide product into the refillable container. In addition, other procedures may be necessary to assure that product integrity is maintained in such cases.

(h) *How must my individual establishments label refillable containers?* Before distributing or selling a pesticide product in a refillable container, a refiller at your establishment must ensure that the label of the pesticide product is securely attached to the refillable container such that the label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. The label and labeling must comply in all respects with the requirements of part 156 of this chapter. In particular, the refiller at your establishment must ensure that the net contents statement and EPA establishment number appear on the label.

(i) *What recordkeeping must my individual establishments do?* Each of your individual establishments that repackages a pesticide product into refillable containers for distribution or sale must maintain all of the records listed in this section in addition to the applicable records identified in parts 167 and 169 of this chapter. The establishment must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe.

(1) For each pesticide product distributed or sold in refillable containers, both of the following records must be maintained for the current operating year and for 3 years after that:

(i) The written refilling residue removal procedure for the pesticide product.

(ii) The written description of acceptable containers for the pesticide product.

(2) Each time a refiller at your establishment repackages a pesticide product into a refillable container and distributes or sells the product, the following records must be generated and maintained for at least 3 years after the date of repackaging:

(i) The EPA registration number of the pesticide product distributed or sold in the refillable container.

(ii) The date of the repackaging.

(iii) The serial number or other identifying code of the refillable container.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

**§ 165.67 Registrants who distribute or sell pesticide products to refillers for repackaging.**

(a) *Must I comply with the standards in this section?* You must comply with the standards in this section if you are a registrant who distributes or sells pesticide products to a refiller that is not part of your company for repackaging into refillable containers.

(b) *Under what conditions can I allow a refiller to repackage my pesticide product into refillable containers?* You may allow a refiller to repackage your pesticide product into refillable containers and to distribute or sell such repackaged product under your existing registration if all of the following conditions are satisfied:

(1) The repackaging results in no change to the pesticide formulation.

(2) One of the following conditions regarding a registered refilling establishment is satisfied:

(i) The pesticide product is repackaged at a refilling establishment registered with EPA as required by § 167.20 of this chapter.

(ii) The pesticide product is repackaged by a refilling establishment registered with EPA as required by § 167.20 of this chapter at the site of a user who intends to use or apply the product.

(3) You have entered into a written contract with the refiller to repackage the pesticide product and to use the label of your pesticide product.

(4) The pesticide product is repackaged only into refillable containers

that meet the standards of subpart C of this part.

(5) The pesticide product is labeled with the product's label with no changes except the addition of an appropriate net contents statement and the refiller's EPA establishment number.

(c) *What violations are applicable to illegal repackaging?* Repackaging a pesticide product for distribution or sale without either obtaining a registration or meeting all of the conditions in paragraph (b) of this section is a violation of section 12 of the Act. Both you and the refiller that is repackaging your pesticide product under written contract with you may be liable for violations pertaining to the repackaged product.

(d) *When must I provide the written contract to the refiller?* If you allow a refiller to repackage your product as specified in paragraph (b) of this section you must provide the written contract referred to in paragraph (b)(3) of this section to the refiller before you distribute or sell the pesticide product to the refiller.

(e) *Am I responsible for product integrity?* Yes, for a product that you distribute or sell to a refiller that is not part of your company for repackaging into refillable containers, you are responsible for the pesticide product not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(f) *What information must I develop?* For each pesticide product distributed or sold in refillable containers, you must develop both of the following documents in writing.

(1) You must develop a refilling residue removal procedure that describes how to remove pesticide residue from a refillable container (portable or stationary pesticide container) before it is refilled.

(i) The refilling residue removal procedure must be adequate to ensure that the composition of the pesticide product does not differ at the time of its distribution or sale from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(ii) If the refilling residue removal procedure requires the use of a solvent other than the diluent used for applying the pesticide as specified on the labeling under "Directions for Use," or if there is no diluent used for application, the refilling residue removal procedure must describe how to manage any rinsate resulting from the procedure in accordance with applicable Federal and State regulations.

(2) You must develop a description of acceptable refillable containers (portable or stationary pesticide containers) that can be used for distributing or selling that pesticide product.

(i) An acceptable container is one that you have determined meets the standards in subpart C of this part and is compatible with the pesticide formulation intended to be distributed and sold using the refillable container.

(ii) You must identify the containers by specifying the container materials of construction that are compatible with the pesticide formulation and specifying information necessary to confirm compliance with the refillable container requirements in subpart C of this part.

(g) *When must I provide the information to the refiller?* You must provide the refiller with all of the following information and documentation before or at the time of distribution or sale of your pesticide product to the refiller:

(1) Your written refilling residue removal procedure for the pesticide product.

(2) Your written description of acceptable containers for the pesticide product.

(3) The pesticide product's label and labeling.

(h) *What recordkeeping must I do?* You must maintain all of the records listed in this section for the current operating year and for 3 years after that. You must furnish these records for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe:

(1) Each written contract entered into with a refiller for repackaging your pesticide product into refillable containers.

## Environmental Protection Agency

## § 165.70

(2) Your written refilling residue removal procedure for the pesticide product.

(3) Your written description of acceptable containers for the pesticide product.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64227, Oct. 29, 2008]

### § 165.70 Refillers who are not registrants.

(a) *Must I comply with the standards in this section?* You must comply with the standards in this section if you are a refiller of a pesticide product and you are not the registrant of the pesticide product.

(b) *Under what conditions can I repack-age a registrant's pesticide product into refillable containers?* A registrant may allow you to repack the registrant's pesticide product into refillable containers and to distribute or sell such repackaged product under the registrant's existing registration if all of the following conditions are satisfied:

(1) The repackaging results in no change to the pesticide formulation.

(2) One of the following conditions regarding a registered refilling establishment is satisfied:

(i) The pesticide product is repackaged at a refilling establishment registered with EPA as required by § 167.20 of this chapter.

(ii) The pesticide product is repackaged by a refilling establishment registered with EPA as required by § 167.20 of this chapter at the site of a user who intends to use or apply the product.

(3) The registrant has entered into a written contract with you to repack the pesticide product and to use the label of the registrant's pesticide product.

(4) The pesticide product is repackaged only into refillable containers that meet the standards of subpart C of this part.

(5) The pesticide product is labeled with the product's label with no changes except the addition of an appropriate net contents statement and the refillers EPA establishment number.

(c) *What violations are applicable to illegal repackaging?* Repackaging a pesticide product for distribution or sale without either obtaining a registration

or meeting all of the conditions in paragraph (b) of this section is a violation of section 12 of the Act. Both you and the pesticide product's registrant may be liable for violations pertaining to the repackaged product.

(d) *Am I responsible for product integrity?* Yes, you are responsible for the pesticide product that you distribute or sell in refillable containers not being adulterated or different from the composition described in its confidential statement of formula that is required under FIFRA section 3.

(e) *What requirements must I follow regarding repackaging a pesticide product into refillable containers?* You must comply with all of the following provisions.

(1) Your establishment must be registered with EPA as a producing establishment as required by § 167.20 of this chapter.

(2) You must not change the pesticide formulation unless you have a registration for the new formulation.

(3) You must repack a pesticide product only into a refillable container that is identified on the description of acceptable containers for that pesticide product provided by the registrant.

(4) You may repack any quantity of a pesticide product into a refillable container up to the rated capacity of the container. In addition, there are no general limits on the size of the refillable containers that you can use.

(5) You must have all of the following items at your establishment before repackaging a pesticide product into any refillable container for distribution or sale:

(i) The written contract referred to in paragraph (b)(3) of this section from the pesticide product's registrant.

(ii) The pesticide product's label and labeling.

(iii) The registrant's written refilling residue removal procedure for the pesticide product.

(iv) The registrant's written description of acceptable containers for the pesticide product.

(6) Before repackaging a pesticide product into any refillable container for distribution or sale, you must identify the pesticide product previously contained in the refillable container to determine whether a residue removal